



# MEMORANDUM

## DEPARTMENT OF HEALTH & HUMAN SERVICES

### Public Health Service

### Food and Drug Administration

### Center for Biologics Evaluation and Research

DATE : January 10, 2006

FROM : William Freas, Ph.D. Will F  
Director, Division of Scientific Advisors and Consultants

SUBJECT: Conflict of Interest Waiver for  
James R. Allen, M.D.

TO : Jason D. Brodsky  
Acting Associate Commissioner for  
External Relations, FDA

Through: Jenny Slaughter  
Director, Ethics and Integrity Staff  
Division of Management Programs, OM

I am writing to request a waiver for James R. Allen, M.D., a Blood Products Advisory Committee member from the conflict of interest prohibitions of 18 U.S.C. 208(a). Dr. Allen has been asked to participate in the meeting of the Blood Products Advisory Committee.

Waivers under section 208(b)(3) may be granted by the appointing official where "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interests involved" and where the individual has made a disclosure of the financial interests at issue. Because you are the appointing official, you have the authority to grant Dr. Allen a waiver under section 208(b)(3).

Section 208(a) prohibits Federal executive branch employees, including special Government employees, from participating personally and substantially in matters in which, to his knowledge, the employee, his spouse, minor children, or general partner: an organization in which he is serving as officer, director, trustee, general partner, or employer, or a person or organization with which he is negotiating for or has arrangement concerning prospective employment has a financial interest. Because Dr. Allen is a special Government employee, he is under a statutory obligation to refrain from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest attributable to him or to his employer.

The function of the Committee, as stated in its Charter, is to advise the Commissioner of the Food and Drug Administration in discharging responsibilities as they relate to assuring safe and effective biological products for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee will discuss rapid tests for detection of bacterial contamination of platelets.

Dr. Allen reported that he is a current member of the [REDACTED]

Under section 208, Dr. Allen is prohibited from participating in any matter affecting these interests, unless he receives a waiver. However, as noted above, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Dr. Allen that would allow him to participate in the discussions before the Committee. The discussion does not involve product approval.

The waiver is justified because the Committee has a special need for Dr. Allen's services because of his unique expertise, experience, and viewpoints with respect to the issue before the Committee. Dr. Allen is the President and Chief Executive Officer, American Social Health Association (ASHA). He served as the Assistant Surgeon General from 1990-1992. He also served as a Commission Corps Officer in the U.S. Public Health Service. In the past, Dr. Allen has held several significant appointments in the Centers for Disease Control and Prevention. During his tenure, as an epidemiologist, he had extensive experience and oversight at the CDC concerning public health initiatives regarding the implementation for the federal AIDS program. Dr. Allen's vast experience in public health related to infectious disease control and environmental controls would greatly enhance the Committee discussions.

For these reasons, I believe Dr. Allen's participation in the deliberations of the Committee will help provide a foundation for developing advice and recommendations that are fair and comprehensive.

Accordingly, I recommend that you grant James R. Allen, M.D. a waiver that would allow him to participate in the discussions before the meeting and any similar meeting where these interests are waivable. I believe that such a waiver is

appropriate because, in this case, the need for Dr. Allen's services outweighs the potential for a conflict of interest created by the financial interest attributable to him.

CONCURRENCE:

/S/  
Jenny Slaughter  
Director, Ethics and Integrity Staff  
Division of Management Programs, OM

1/21/06  
Date

DECISION:

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Waiver granted based on my determination, made in accordance with section 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.

Waiver denied.

/S/  
Jason D. Brodsky  
Acting Associate Commissioner for  
External Relations FDA

1-24-06  
Date